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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,432	12/27/2001	Abu Alam	207324	2519

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LEYDIG VOIT & MAYER, LTD  
TWO PRUDENTIAL PLAZA, SUITE 4900  
180 NORTH STETSON AVENUE  
CHICAGO, IL 60601-6780

EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT PAPER NUMBER

3737

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/034,432	Applicant(s) ALAM ET AL.	
	Examiner Shawna J. Shaw	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/27/01, 4/1/02, 5/23/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/1/02, 5/23/02</u>                                                       | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-11, 22-38 and 46-96 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. An inventive diluent comprising a solubizer and alcohol that is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification does not adequately disclose the use of an aqueous diluent absent a solubizer and alcohol that exhibits the same ICG concentration properties without undue experimentation.
2. Claims 1-11, 22-38 and 46-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an indocyanine green (ICG) composition comprising an inventive aqueous diluent comprised of a solubizer and alcohol (¶s 0019, 0022-28) does not reasonably provide enablement for an enhanced concentration ICG composition that is stable for at least 24 hours comprised of just any aqueous diluent (e.g., water). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification does not

adequately disclose the use of an aqueous diluent absent a solubizer and alcohol that exhibits the same ICG concentration properties without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1-96, the scope of the term "stable"/"stability" cannot be ascertained because it is a relative term. In addition, various extraneous conditions (i.e., amount of light exposure, heat, etc.) may alter the stability of a composition having the same concentration.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 24, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Flower '199 of record.

Regarding claims 1-3, Flower et al. discloses an ICG composition of 12.5 mg/ml of ICG administered to the blood stream of a subject (col. 6 – col. 7 line 10).

Regarding claims 24, 29 and 30, Flower et al. discloses administering an ICG composition of 12.5 mg/ml of ICG to the blood stream of a subject (col. 6 – col. 7 line 10).

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 52, 54, 62, 66, 68, 69, 76, 80-82 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeimer in view of Flower '199 of record.

Regarding claims 52, 54, 62, 66, 68, 69, 76, 80-82 and 92, Zeimer et al. teaches co-applying ICG (col. 6 lines 52-59) and a liposomal preparation (col. 10 lines 45-55) to the blood stream of a patient to obtain choroidal neovascularization (CNV) angiographic images (col. 11 lines 29-33) and provide treatment (e.g., reduce rate of blood flow). See also claims 1 and 25. Zeimer differs from the claimed invention in that the concentration of the fluorescent dye is not explicitly addressed. Flower demonstrates that concentrations of 12.5 mg/ml of ICG are known to aid in enhanced

observation of choroidal circulation (col. 6 – col. 7 line 10). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use a concentration of at least about 10 mg/ml of ICG as taught by Flower in the invention as taught by Zeimer for the above stated reasons.

6. Claims 53, 55, 63, 67, 77, 83-85, 93 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeimer in view of Flower '199 of record and further in view of EP 0 589 825 of record.

Regarding claims 53, 55, 63, 67, 77, 83-85, 93 and 96, Zeimer and Flower differ from the claimed invention in that an endoscope is not explicitly addressed. EP 0 589 825 discloses an ophthalmologic examination and treatment apparatus including an endoscope (150, fig. 4) for more efficient light application. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use an endoscope as taught by EP 0 589 825 in the invention as taught by Zeimer in view of Flower for the above stated reasons.

7. Claims 19-21, 26-28, 48, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flower '199 of record in view of Zeimer and further in view of Melhorn '957 of record.

Regarding claims 19-21, 26-28, 48, 49 and 51, Flower differs from the claimed invention in that liposomes are not specifically addressed. Zeimer teaches the use of liposomes for selective and targeted delivery of indocyanine green. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use liposomes to deliver ICG to the choroidal vasculature as taught by Zeimer in the

invention as taught by Flower to provide more selective control of the diagnostic/therapeutic procedure. Zeimer and Flower further differ from the claimed invention in that a multiple chambers for isolating the ICG composition prior to mixture with a liposomal preparation are not addressed. Melhorn generally demonstrates the well-known use of e.g., a dual chambered syringe and/or vials (fig. 1, 2) for isolating an injectable substance until just prior to mixture with lipid carriers and subsequent administration to a subject to achieve high degrees of loading with simple and economical procedures. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to utilize a dual-chambered device as taught by Melhorn in the invention as taught by Flower in view of Zeimer for the above stated reasons.

8. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flower '199 of record in view of Zeimer and further in view of Melhorn '957 of record (as applied to claim 49 above) in view of Shibamura et al.

Regarding claim 50, the above mentioned inventions differ from the claimed invention in that an ICG lyophilizate is not explicitly addressed. Shibamura et al. demonstrates that ICG compositions in lyophilizate form before mixture with a reactive diluent are well known [0046, 0063]. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to a lyophilized ICG composition mixed with a diluent as disclosed by Shibamura et al. in the invention as taught by Flower in view of Zeimer and Melhorn as is well known in the art for its prolonged usefulness.

9. Claims 22, 25 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flower '199 of record in view of Shibamura et al.

Regarding claims 22, 25 and 46, Flower differs from the claimed invention in that an ICG lyophilizate is not explicitly addressed. Shibamura et al. demonstrates that ICG compositions in lyophilizate form before mixture with a reactive diluent are well known [0046, 0063]. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to a lyophilized ICG composition mixed with a diluent as disclosed by Shibamura et al. in the invention as taught by Flower as is well known in the art for its prolonged usefulness.

10. Claims 23 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flower '199 of record in view of Shibamura et al. (as applied to claims 22 and 46 above) and further in view of Zeimer.

Regarding claims 23 and 47, Flower and Shibamura differ from the claimed invention in that liposomes are not specifically addressed. Zeimer teaches the use of liposomes for selective and targeted delivery of indocyanine green. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use liposomes to deliver ICG to the choroidal vasculature as taught by Zeimer in the invention as taught by Flower to provide more selective control of the diagnostic/therapeutic procedure.

***Allowable Subject Matter***

11. Claims 4-18, 31-45, 56-61, 64, 65, 70-75, 78, 79, 86-91, 94 and 95 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second

paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

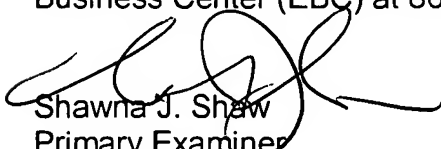
**Conclusion**

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Maarek et al. "Fluorescenc of indocyanine green in blood" demonstrates that stability of ICG solutions depend on several extraneous factors such as temperature and light exposure (p. 157).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sykes Angela can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shawna J. Shaw  
Primary Examiner  
8/5/2004